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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,058

06/21/2006

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002.00270

2111

35876 7590 03/13/2008
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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

03/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,058	Applicant(s) HARDIE ET AL.	
	Examiner SHERIDAN SWOPE	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14, 16, 19-29 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-12, 14, 16, 19-29 and 31-35 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

It is noted that the original claim set of January 17, 2006 included Claims 1-39. The amended claim set filed January 17, 2006 does not list Claim 36-39, which is improper. Every claim set must state the status of all filed claims. Any subsequent claim set not stating the status of all filed claims will be considered to be non-responsive.

Claims 1-12, 14, 16, 19-29, 31-35 are pending.

Priority

If Applicants wish to perfect their claim to priority to foreign applications UK 0316725.1 and UK 0330078.7, said applications should be filed.

Information Disclosure Statement

It is noted that Applicants have filed five (5) Information Disclosure Statements encompassing 248 references. It is desirable to avoid the submission of long lists of documents if it can be avoided. Where a long list is submitted, Applicants are requested to point out those documents which are known to be of the most significance to the elected invention. This request is in accord with dicta from *Molins PLC v. Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995), which states that forcing the Examiner to find "a needle in a haystack" is "probative of bad faith." *Id.* at 1888.

Applicants are advised that all citations are to include an author and date and, where relevant, journal name, volume and page numbers.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1, 2, 19, and 20 drawn to a method for identifying a LKB1 modulator in the presence of STRAD and/or MO25 and a composition comprising LKB1, STRAD, and MO25.

Group II, Claims 3-5 and 16, drawn to a composition comprising LKB1, STRAD, and MO25.

Group III, Claims 6-12, drawn to a cell capable of expressing LKB1, STRAD, and MO25.

Group IV, Claim 14, drawn to a cellular method for making a composition comprising LKB1, STRAD, and MO25.

Group V, Claims 21, 22, 31, 32, drawn to a kit comprising isolated LKB1, STRAD, and MO25.

Group VI, Claims 23 and 24, drawn to a method for over-expressing LKB1.

Group VII, Claims 25 and 26, drawn to a method for identifying a MO25 binding partner.

Group VIII, Claims 27 and 28, drawn to a method for identifying a MO25 genetic defect in PJS.

Group IX, Claim 29, drawn to a method for identifying activators of AMPK.

Group X, Claims 33 and 34, drawn to a peptide substrate for LKB1.

Group XI, Claim 35, drawn to an antibody.

For each of Inventions I, X, and XI above, restriction to one of the following is also required. Therefore, election is required of one of Inventions I-XI and, if Invention I, X, or XI is elected, one of Inventions (A)-(CC).

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If Invention I is elected, elect one of:

- (A.) An in vitro method
- (B.) A cellular method

If Invention X is elected, elect one of:

- (C.) SEQ ID NO: 16
- (D.) SEQ ID NO: 17
- (E.) SEQ ID NO: 18
- (F.) SEQ ID NO: 19
- (G.) SEQ ID NO: 20
- (H.) SEQ ID NO: 21
- (I.) SEQ ID NO: 23
- (J.) SEQ ID NO: 24
- (K.) SEQ ID NO: 25
- (L.) SEQ ID NO: 29
- (M.) SEQ ID NO: 31
- (N.) SEQ ID NO: 33
- (O.) SEQ ID NO: 35
- (P.) SEQ ID NO: 37

If Invention XI is elected, elect one of:

- (Q.) SEQ ID NO: 38
- (R.) SEQ ID NO: 39
- (S.) SEQ ID NO: 40

- (T.) SEQ ID NO: 41
- (U.) SEQ ID NO: 42
- (V.) SEQ ID NO: 43
- (W.) SEQ ID NO: 44
- (X.) SEQ ID NO: 45
- (Y.) SEQ ID NO: 46
- (Z.) SEQ ID NO: 47
- (AA.) SEQ ID NO: 48
- (BB.) SEQ ID NO: 49
- (CC.) SEQ ID NO: 50

The inventions listed as Groups I-XI(A)-(CC) do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The technical feature linking Groups I-XI appears to be that they all relate to the LKB1-mediated pathway. However, the LKB1-mediated pathway was known in the art. Moreover, Fryer et al, 2002 teach a method for identifying AMPK inhibitors, which anticipates Claim 29. Therefore Groups I-XI share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, the products of Groups II, III, V, X(C)-(P), and XI(Q)-(CC) do not share a special common structural and functional feature while, the methods of Groups I(A)-(B), IV, and VI-IX do not use the same reagents or produce the same results. In addition, the methods of Groups I(A)-(B), IV, and VI-IX do not comprise all of the methods for making or using the products of Groups II, III, V, X(C)-(P), and XI(Q)-(CC). Accordingly, Groups I-

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XI(A)-(CC) are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Searching more than one of Groups I- XI(A)-(CC) would represent a burden on the Office for the following reasons. Because the products of Groups II, III, V, X(C)-(P), and XI(Q)-(CC) do not share a special structural and functional feature, a search for any one said product would not encompass a search for any other said products. Thus, a search for more than one of the products of Groups II, III, V, X(C)-(P), and XI(Q)-(CC) would be a burden on the Office. A search for any one of the methods of Groups I(A)-(B), IV, and VI-IX would not encompass a search for any other said methods because the methods do not share a special technical feature of steps and products used, or results produced. Thus, the search for more than one of Groups I(A)-(B), IV, and VI-IX would be a burden on the Office. A search of any one of the products of Groups II, III, V, X(C)-(P), and XI(Q)-(CC) would not encompass a search of any of the methods of Groups I(A)-(B), IV, and VI-IX, or vice versa, because said methods are not the only methods of making or using said products. Thus, a search of any one of the products of Groups II, III, V, X(C)-(P), and XI(Q)-(CC) with any of the methods of Groups I(A)-(B), IV, and VI-IX would be a burden on the Office.

The searches for any one invention are not required for and are not coextensive with the searches for any other invention, thereby creating an undue burden of search and examination. The results from a search of each of these inventions have different considerations with respect to the prior art. Burden lies not only in the search of U.S. patents, but also in the search for literature and foreign patents and in examination of the claim language and specification for

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compliance with the statutes concerning new matter, distinctness, written description and enablement.

These inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification. Furthermore, as explained above, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper. If Applicants should traverse the restriction based on an argument that inventions are not distinct, they should provide evidence as to why the restricted inventions are obvious over their elected invention

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim

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will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/

Primary Examiner, Art Unit 1652